Quality, Regulatory Affairs, Medical Device & IT

mediteq FORUM

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Mediteq Forum Träff

- China in your hand

Entering the Chinese market is a tremendous opportunity but can also be a daunting experience for medical device manufacturers. Having a partner with experience and expertise in the Chinese marketplace is essential and can be the difference between success and failure.

During this Mediteq Forum activity our guest Tracy Tu from BradyKnows Medical will provide insight into the regulatory requirements for China and in particular the changes introduced in the New Fundamental Medical Device Regulations Order No. 739 that was released in 2021. We will learn more about practical implications on registrations; clinical investigations, documentation required, need of local representatives etc.

Date: 4th October 2022
Time: 4 - 6 pm
Digital: Zoom link will be sent closer to the date
Sign up: here

The presentation will be held in English and cover the China regulation as described above and there will also be a chance for the participants to ask questions.

Please send in your questions ahead of time if you have specific issues, you'd like the expert to cover.

Welcome!

Petra Rosén & Emilie Andersson
Facilitators, Mediteq Forum

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Presentation of today's guest

Tracy Yu, Senior Project Manager
BradyKnows Medical

Tracy Yu is a regulatory and clinical research professional with nearly a decade of expertise. Her responsibilities include the development of regulatory and clinical strategies and management of pre-market approval projects from planning to completion, covering type testing, clinical trials/CER, consultation meeting with China NMPA reviewer, and post-market inspection and China localization projects.